Serial No.: 09/524,747 Amendment

December 20, 2004

## REPLACEMENT CLAIM SET

This listing of claims will replace all prior versions and listings of claims in this application.

- 1-19 (canceled)
- 20. (currently amended) A method for obtaining an average T<sub>max</sub> of <u>diclofenac Diclofenac</u> Diclofenac after in a human patient between 5 and 30 minutes after following of administering said

  diclofenac to said administration to in a human patient—in need of such a treatment, said average

  T<sub>max</sub> having a coefficient of variation (CV%) lower less than about 70%, which comprises

  comprising orally administering a diclofenac formulation to said patient, wherein said diclofenac formulation comprises diclofenac pharmaceutical formulation containing Diclofenae in acid and/or salt form together with an alkali metal bicarbonate selected from the group consisting of sodium bicarbonate, potassium bicarbonate and mixtures thereof—and customary excipients and adjuvants, wherein said alkali metal bicarbonate is present in an amount of from about 20 to about 80% by weight based on the weight of said diclofenac, Diclofenae and wherein said diclofenac formulation pharmaceutical formulation further contains a flavoring substance selected from the group consisting of mint, aniseed, ammonium glycyrrhizinate and mixtures thereof whereby palatability and astringency effects are eliminated, and wherein said diclofenac formulation is selected from:
- a. a powder formulation dissolved or dispersed in water; and
- b. a fast release layer present in a two layered diclofenac tablet that comprises a slow release layer and a fast release layer.
- 21. (currently amended) ★ The method according to of claim 20 where said average T<sub>max</sub> of Dielofenae is reached after 13-27 minutes after since said administration.
- 22. (canceled)
- 23. (currently amended) A The method according to of claim 22 20 wherein said alkali metal bicarbonate is present in an amount of from about 40 to about 80% by weight based on the weight of said diclofenac Diclofenac.
- 24. (canceled)
- 25. (canceled)
- 26. (canceled)

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- 27. (canceled)
- 28. (canceled)
- 29. (currently amended) ★ The method according to of claim 20 wherein said diclofenac formulation comprises from about 10 to about 60 mg. of diclofenac Diclofenac is present in its potassium and/or sodium salt form.
- 30. (new) The method of claim 20 wherein said diclofenac formulation comprises from about 10 to about 60 mg. of diclofenac in its sodium sait form.
- 31. (new) The method of claim 20 wherein said alkali metal bicarbonate is sodium bicarbonate.
- 32. (new) The method of claim 20 wherein said alkali metal bicarbonate is potassium bicarbonate.
- 33. (new) The method of claim 20 wherein said diclofenac formulation is said powder formulation.
- 34. (new) The method of claim 20 wherein said diclofenac formulation is said fast release layer.
- 35. (new) The method of claim 20 wherein said diclofenac formulation is said powder formulation, and said diclofenac formulation comprises about 50 mg. of diclofenac potassium salt.
- 36. (new) The method of claim 20 wherein said diclofenac formulation is said fast release layer, said diclofenac formulation comprises about 15 mg. of diclofenac potassium salt, and said slow release layer comprises about 70 mg. of diclofenac potassium salt.
- 37. (new) The method of claim 20 wherein said diclofenac formulation comprises about 50 mg. of diclofenac potassium salt and from about 22 to about 24 mg. of potassium bicarbonate.
- 38. (new) The method of claim 20 wherein said diclofenac formulation comprises about 50 mg. of diclofenac and said administration achieves an average  $C_{\text{max}}$  of from about 1700 to about 2300 ng/ml.
- 39. (new) A method of treating a human patient with diclofenac comprising orally administering a diclofenac formulation to said patient, wherein said diclofenac formulation comprises diclofenac in acid and/or salt form together with one or more alkali metal carbonates or bicarbonates, wherein said one or more alkali metal carbonates or bicarbonates is present in an

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amount of greater than about 20% by weight based on the weight of said diclofenac, and wherein said diclofenac formulation is selected from:

- a. a powder formulation dissolved or dispersed in water; and
- b. a fast release layer present in a two layered diclofenac tablet that comprises a slow release layer and a fast release layer.
- 40. (new) The method of claim 39 wherein an average T<sub>max</sub> of diclofenac is reached between 5 and 30 minutes after orally administering said diclofenac formulation.
- 41. (new) The method of claim 39 wherein an average  $T_{max}$  of diclofenac is reached between 5 and 30 minutes after orally administering said diclofenac formulation, said average  $T_{max}$  having a coefficient of variation (CV%) less than about 70%.
- 42. (new) The method of claim 39 wherein said diclofenac formulation comprises about 50 mg. of diclofenac and said administering achieves an average  $C_{\text{max}}$  of from about 1700 to about 2300 ng/ml.
- 43. (new) The method of claim 39 wherein said diclofenac formulation comprises from about 10 to about 60 mg. of diclofenac in its potassium salt form.
- 44. (new) The method of claim 39 wherein said diclofenac formulation comprises from about 10 to about 60 mg. of diclofenac in its sodium salt form.
- 45. (new) The method of claim 39 wherein said one or more alkali metal carbonates or bicarbonates is present in an amount of from about 40 to about 80% by weight based on the weight of diclofenac.
- 46. (new) The method of claim 39 wherein said diclofenac formulation comprises sodium bicarbonate.
- 47. (new) The method of claim 39 wherein said diclofenac formulation comprises potassium bicarbonate.
- 48. (new) The method of claim 39 wherein said diclofenac formulation is said powder formulation.
- 49. (new) The method of claim 39 wherein said diclofenac formulation is said fast release layer.

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50. (new) The method of claim 39 wherein said diclofenac formulation is said powder formulation, and said diclofenac formulation comprises about 50 mg. of diclofenac potassium salt.

- 51. (new) The method of claim 39 wherein said diclofenac formulation is said fast release layer, said diclofenac formulation comprises about 15 mg. of diclofenac potassium salt, and said slow release layer comprises about 70 mg. of diclofenac potassium salt.
- 52. (new) The method of claim 39 wherein said diclofenac formulation comprises about 50 mg. of diclofenac potassium salt and from about 22 to about 24 mg. of potassium bicarbonate.
- 53. (new) A method for obtaining an average T<sub>max</sub> of diclofenac in a human patient between 5 and 30 minutes after administration comprising orally administering a diclofenac formulation to said patient, wherein said diclofenac formulation comprises diclofenac in acid and/or salt form, and wherein said diclofenac formulation is selected from:
  - a. a powder formulation dissolved or dispersed in water; and
- b. a fast release layer present in a two layered diclofenac tablet that comprises a slow release layer and a fast release layer.
- 54. (new) The method of claim 53 wherein said average  $T_{max}$  has a coefficient of variation (CV%) less than about 70%,
- 55. (new) The method of claim 53 wherein said average  $T_{max}$  is reached 13-27 minutes after administration.
- 56. (new) The method of claim 53 wherein said diclofenac formulation comprises about 50 mg. of diclofenac and said administration achieves an average  $C_{\text{max}}$  of from about 1700 to about 2300 ng/ml.
- 57. (new) The method of claim 53 wherein said diclofenac formulation is said powder formulation.
- 58. (new) The method of claim 53 wherein said diclofenac formulation is said fast release layer.
- 59. (new) A method for obtaining an average T<sub>max</sub> of diclofenac in a human patient between 5 and 30 minutes after administration comprising orally administering a diclofenac formulation to said patient, wherein said diclofenac formulation comprises diclofenac in acid and/or salt form

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and means for enhancing said average  $T_{max}$  of said diclofenac, and wherein said diclofenac formulation is selected from:

- a. a powder formulation dissolved or dispersed in water; and
- b. a fast release layer present in a two layered diclofenac tablet that comprises a slow release layer and a fast release layer.
- 60. (new) The method of claim 59 wherein said average  $T_{max}$  has a coefficient of variation (CV%) less than about 70%.
- 61. (new) The method of claim 59 wherein said  $T_{max}$  of diclofenac is reached 13-27 minutes after administration.
- 62. (new) The method of claim 59 wherein said diclofenac formulation comprises about 50 mg. of diclofenac and said administration achieves an average  $C_{max}$  of from about 1700 to about 2300 ng/ml.
- 63. (new) The method of claim 59 wherein said means for enhancing said average  $T_{\text{max}}$  of said diclofenac comprises one or more alkali metal carbonates or bicarbonates.
- 64. (new) The method of claim 59 wherein said means for enhancing said average T<sub>max</sub> of said diclofenac comprises one or more alkali metal carbonates or bicarbonates in an amount of from about 20 to about 80% by weight based on the weight of said diclofenac.
- 65. (new) The method of claim 59 wherein said means for enhancing said average  $T_{\text{max}}$  of said diclofenac comprises sodium bicarbonate.
- 66. (new) The method of claim 59 wherein said means for enhancing said average  $T_{max}$  of said diclofenac comprises potassium bicarbonate.
- 67. (new) The method of claim 59 wherein said diclofenac formulation is said powder formulation.
- 68. (new) The method of claim 59 wherein said diclofenac formulation is said fast release layer.